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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,040	12/06/2006	Joachim Nozulak	VAND-0030-US	5957

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HOFFMAN WARNICK LLC
75 STATE STREET
14TH FLOOR
ALBANY, NY 12207

EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
05/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOCommunications@hoffmanwarnick.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,040	NOZULAK ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of group I, claims 1-12 in the reply filed on Feb. 14, 2010 is acknowledged.

Claims 1-12 are prosecuted. Claims 13-20 are withdrawn from consideration.

2. Claim 2, 10-12 recites the limitation "method of claim 1" or "compound of claim 7". There is insufficient antecedent basis for this limitation in the base claim. Please note that the base claim 1 is a compound claim and there is no antecedent basis for "method". While the base claim 7 is a method not a compound.

The term "includes" "suitable" etc. in claims 2-4, 8-10 is a relative term which renders the claim indefinite. Please note that claims 2 and 8 use the term "includes" which make the scope ambiguous whether the base claim contains "pharmaceutically" acceptable acid. It is recommended that to further limit the acids of claim 1, the format "....claim 1 "wherein the acid of the addition salt is a pharmaceutically acceptable acid"

The term "suitable" is a subjective quantity, suitable for one person may not be suitable for another. It is unclear whether claims 3-4, 9-10 is the innate nature of the biological activity or a "therapeutically effective amount" of the compound in a composition for therapeutic use. If it is the innate nature, then, they are essential duplicates of the base claims 1 and 7. If they are limited to a "therapeutically effective amount" of the compound in a composition for therapeutic us, then, it is a pharmaceutical composition.

Claims 5-6 and 11-12 are also ambiguous since it is unclear whether they are innate nature of the compound or pharmaceutical composition. If they are essential duplicates, then, duplicate claims are subject to double patenting rejection upon allowance of one set of the claims. It is recommended, the additional duplicate claims be canceled. MPEP 706.12(k).

3. Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing the process to obtain the compound, does not reasonably provide enablement for "pharmaceutical composition". Please note while pharmaceutical composition of the dependent claims is conventional technique but it is broadening of the base

claims and the extra steps of making the composition with additional material are lacking in the base claim.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strupczewski et al. US 5,364,866 in view of Corbett et al. p.136, Caccia et al. p.401 or Subramanian et al. (p.559) and Garattini et al. further in view of Bungaard and Waller

Determination of the scope and content of the prior art (MPEP §2141.01)

Strupczewski et al. '866 disclosed composition of the parent drug iloperidone and its composition which is tantamount to a claim to all its metabolite.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Corbett et al. Caccia et al. or Subramanian et al. disclosed that the circulating metabolite P88 is active in receptor binding and brain uptake. Further, it is taught by Garattuni that, drug metabolite, if active would be inherently enhancing/prolonging the drug activity, therefore, the free hydroxyl compound is a drug. Bungaard (p.1-3) and Waller (p.498) taught that acylation of a hydroxyl group is routine, conventional prodrug formulation.

Finding of prima facie obviousness---rational and motivation (MPEP§2142-2143)

Therefore, one having ordinary skill in the art in possession of the generically claimed iloperidone would be motivated to isolate the specific "most active" metabolite with the under standing that it is also a "drug". Formulation of a hydroxyl containing drug with an acylated ester is routine, conventional design choice of prodrug formulation.

5. Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-3 of copending Application No. 12/403,735 in view of Corbett et al. p.136, Caccia et al. p.401 or Subramanian et al. (p.559) and Garattini et al. further in view of Bungaard and Waller.

The same rational as delineated in section 4 is also applicable and hereby incorporated by reference.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Apr.28, 2010

/Celia Chang/
Primary Examiner
Art Unit 1625